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Summary of Risk Assessment on Polychlorinated Biphenyls for Outboard Marine Corporation Site

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1. Background

This document summarizes a study which presents a comparative risk assessment of two alternative remedial actions for the cleanup of PCBs[1] in the vicinity of Waukegan Harbor (Figure 1), which is located on Lake Michigan 37 miles north of Chicago. Elevated levels of PCBs have been detected in the sediment and soil in several locations near the harbor. Industrial facilities located in the area include Outboard Marine Corporation (OMC), Larsen Marine, a National Gypsum plant, Falcon Marine, and the Waukegan Water Filtration plant. A public beach is located on the eastern edge of the OMC property. Public launching ramps, mooring sites, slips, and other facilities for small boats are also located in the harbor, primarily in the southern portion. Various fish species are found in the Waukegan area of Lake Michigan, many of which are valuable to sport and commercial fishing industries.

It appears that, beginning in the late 1950's, OMC utilized hydraulic fluids containing PCBs in its die-casting facility, OMC plant #2, located just north of Slip #3 (Figure 1). In 1976, the U. S. Environmental Protection Agency (USEPA) notified OMC that it had found high concentrations of PCBs in the sediment and water of Waukegan Harbor as well as in the soil in the vicinity of the OMC plant. Since the

[1]Polychlorinated biphenyls (PCBs) are comprised of mixtures of biphenyl compounds with varying amounts of chlorine. Commercial PCBs, due to their resistance to breakdown from fire and heat and their electrical insulating capacity, had been widely used in numerous industrial applications since their introduction in the 1920s. PCBs were identified as a potentially hazardous environmental contaminant during the 1960s. In 1971 the principal manufacturer of PCBs voluntarily ceased PCB production for all "open-ended" applications (applications where emissions into the environment cannot be controlled), and completely discontinued production in 1977 (IARC, 1978 and Monsanto Company, 1979 In: James *et al.*, 1981).

discovery of PCBs on the OMC site, many studies have been undertaken to determine PCB concentrations and export of PCBs from the site, and the potential impact of PCBs originating from this site on the environment. These investigations have revealed three major areas with elevated levels of PCBs: Waukegan Harbor, particularly Slip #3; the surface runoff drainage area called the North Ditch, which includes the Crescent Ditch and Oval Lagoon; and a parking lot north of the OMC plant (Figure 1).

Utilizing the information gathered from this site, results of transport modelling for the site, and knowledge of environmental properties of PCBs, the EPA has determined that remedial actions in the Waukegan Harbor, the North Ditch area and the parking lot area of the OMC property are needed. The remedial action plan selected by the EPA was described in its Record of Decision (USEPA, 1984). The proposed plan, herein referred to as the ROD alternative, is a fund-balanced approach that the EPA expects to be effective in preventing migration of PCBs from the site. This alternative calls for removal of all sediments and soil containing more than 10,000 parts per million (ppm) PCBs to a licensed hazardous waste facility, and for on-site containment of all sediments and soil contaminated with between 50 and 10,000 ppm PCBs in a containment cell located on the OMC parking lot.

In addition to the ROD remedial action proposed by the EPA, an in-place containment (IPC) alternative is also evaluated. The IPC alternative proposes to confine on site all sediments in Waukegan Harbor contaminated with more than 50 ppm PCB in a containment cell located at the present site of Slip #3. This summary briefly discusses the findings of a comparative assessment of the risk to human health from exposure to PCBs under these two remedial alternatives. The reader is referred to the main document for a more thorough exposition of procedures and results. The intent of the risk assessment provided in the main document is to supply information that can be used to assess benefits and costs of these remedial alternatives.

2. Evaluation of Potential Health Risks

Evaluation of the potential for health risks is a three step process consisting of exposure assessment, hazard assessment, and risk characterization. Exposure assessment is the estimation of the amount of PCBs to which humans are expected to be exposed in each of the remedial alternatives studied. Hazard assessment is the qualitative evaluation of experimental data to determine the potential of developing adverse health effects as a result of exposure to PCBs. Risk characterization is the estimation, based upon the data evaluated in the hazard assessment step, of any increased risks to human health from the exposures estimated in the exposure assessment.

The evidence that PCBs have the potential for causing some health effects is derived principally from animal studies. As with any substance, the potential for adverse health effects is determined by both the degree of exposure and the potency of the substance for causing the effects. Therefore, risk depends not only on the potency or intrinsic toxicity of PCBs (that is, the amount of PCBs required to produce harm), but also the amount of PCBs to which humans are exposed. Accordingly, in the assessment both the potency of PCBs for causing various health effects and the expected exposures to humans as a result of each of the remedial actions are evaluated.

There is considerable uncertainty as to both the extent of human exposure to PCBs from the Waukegan Harbor area and the effects upon human health as a result of this exposure. Actual measurements of environmental releases and human exposures are not available for all exposure routes even under present conditions, and clearly are not available for the remedial action scenarios being evaluated. Therefore, exposures are estimated using mathematical models that require informed judgments regarding the specific remedial actions and environmental conditions. Additional uncertainty results from quantifying the potential for human health effects using experimental animal data.

Mathematical dose response models are used to estimate the effect of environmental exposures upon humans using data on animals exposed to much larger doses of PCBs. Such application of mathematical models is frequently made by the regulatory communities. In the risk assessment, these exposure and dose response models are an integral part of the evaluation of projected site responses under competing management alternatives.

Elements of uncertainty that are inherent in these analyses are addressed by providing two types of estimates: "more probable" and "worst case." "More probable" estimates involve use of reasonable, best estimate values for parameters derived from theory, data, and model results. These estimates are intended to represent best professional judgment regarding likely exposures and resulting risks. "Worst case" estimates are intended to provide reasonable upper bounds to PCB exposures and resulting risks to humans. These estimates are based upon data from among the higher postulated exposure levels rather than more likely levels; similar conservative approaches are used in estimating dermal uptake rates, bioaccumulation factors, and other biological, chemical and physical constants. In addition, care is taken to make the analyses of the two alternative actions comparable by using identical or similar approaches and assumptions in evaluating both remedial alternatives, insofar as is appropriate. As a result, there should be less uncertainty in estimates of relative levels of risk between the alternative remedial actions than in estimates of absolute levels of risk. Details of the assumptions and approaches used in estimating human exposure and risk are fully discussed and documented in the main document and are only briefly discussed in this summary.

The elements of uncertainty in the risk assessment process discussed above imply that there is considerable uncertainty in the numerical estimates obtained. Presently, there is no direct, definitive evidence that adverse health effects will occur in humans from PCBs from the Waukegan Harbor area at exposure levels which may result from potential residual PCB concentrations remaining after remediation, as estimated in this assessment. Nevertheless, we believe this assessment can be of considerable value, particularly in evaluating the relative merits of the ROD and IPC remedial alternatives. Because of the conservatism inherent in several aspects of this assessment, we expect any risks that are present are likely to be lower than estimated. EPA risk assessment methods were largely followed in this assessment, with the only variation of consequence being in the animal to human extrapolation process for carcinogenesis. This variation, which is described in the risk characterization section, was considered to be supported by the scientific evidence and is used by other regulatory agencies. Comparisons between the ROD and IPC are unaffected by this variation.

3. Exposure Assessment

Estimation of human exposure due to PCB contamination at Waukegan Harbor and in its vicinity is an involved process. It requires judgments regarding the specific procedures to be followed in the remedial actions; it requires simulation and forecasting of the levels of PCBs in the different environmental compartments (air, the water column, the underlying sediment, and fish) for the remedial alternatives under consideration; and it requires judgments about human behavior regarding such activities as fishing, fish consumption, boating activities, swimming, etc.

3.1. Description of Remedial Alternatives

The water column and sediment of Waukegan Harbor and the North Ditch area have been found to contain elevated concentrations of PCBs. Although Slip #3 comprises only 3% of the total harbor area, an estimated 98% of the total PCBs in the harbor are found there, with the highest levels occurring in the western end of the slip. In general, harbor PCB concentrations tend to decrease with distance from Slip #3. PCB levels in the harbor sediment range from concentrations as high as 500,000 parts per million (ppm) in the western end of Slip #3 to less than 10 ppm at the mouth of the harbor. The spatial average PCB concentration in the harbor sediment in Slip #3 is approximately 10,500 ppm, while the average concentration in the remainder of the upper harbor is approximately 100 ppm. Sediments in the Crescent Ditch and Oval Lagoon include PCB-contaminated "pockets" containing concentrations as high as 50,000 ppm

PCBs, with PCB levels decreasing to an average of 200 ppm in the East-West Channel area.

Presently, the major source of PCBs in the water in Waukegan Harbor and the North Ditch area is the underlying sediment; therefore, the general spatial concentration trends in the water column reflect those of the sediments. In 1980, the average PCB concentrations in the water column ranged from 0.51 parts per billion (ppb) in Slip #3 to 0.15 ppb in the outer harbor, and approximately 7 ppb in the North Ditch. Groundwater samples from the Crescent Ditch/Oval Lagoon area are reported to show significant levels of PCBs and this source may contribute to the concentrations in the North Ditch.

Record of Decision Alternative (ROD): Under the ROD alternative, all sediments in Waukegan Harbor and the North Ditch area containing greater than 50 ppm PCBs will be removed and confined to prevent migration of PCBs into the environment. The sediments containing the highest concentrations of PCBs (those containing greater than 10,000 ppm PCBs) will be removed and disposed of offsite in a hazardous waste facility. Sediments with lower PCB concentrations will be dredged, dewatered in clay-lined lagoons to be constructed on vacant OMC property, and ultimately confined in containment cells to be constructed on the OMC parking lot and in the Crescent Ditch/Oval Lagoon areas. The containment cell to be constructed on the parking lot will also serve to confine the soil beneath the pavement of the parking lot. The exact construction designs, and schedule for implementation of this remedial action alternative have not yet been completed, but the general implementation plans of the existing plan of action are contained in the EPA Record of Decision.

<u>In-Place Containment Alternative (IPC)</u>: An alternative plan, the In-Place Containment (IPC), proposes to confine, on site, all sediments in Waukegan Harbor containing more than 50 ppm PCB. Under this alternative, a containment cell will be built by constructing a slurry wall between Slip #3 and the upper harbor. The upper harbor will be dredged to remove all sediments containing greater than 50 ppm PCBs and the dredged material will be deposited behind the slurry wall. A high volume water treatment plant will be employed to remove PCBs from the water before returning it to the harbor, after which Slip #3 will be capped with impermeable clay. It is also proposed that a storm drain be constructed through the parking lot to divert surface runoff and process cooling water away from the North Ditch area and into Lake Michigan. All excavated material will be placed in the Crescent Ditch. The entire North Ditch area will then be temporarily dewatered so that the sediment can be capped with clay and covered with top soil and vegetation. The soil in the parking lot will remain undisturbed. Monitoring wells will be constructed in the vicinity to detect any transport of PCBs out of the North Ditch area. The hydrogeology in the immediate area is projected to be significantly altered as a result of filling in the North Ditch. Therefore, monitoring of the groundwater is planned to assess the need for further remedial action to prevent migration of PCBs through the groundwater.

3.2. Environmental Modelling

Assessment of risk to human health and to the environment due to the PCBs in Waukegan Harbor and its vicinity requires simulation and forecasting of the levels of PCBs in the different environmental compartments. Some of the possible routes of human exposure to PCBs are dermal contact, inhalation, drinking water, and ingestion of fish. PCBs are known to accumulate in fish with the result that the concentration of PCBs in fish exceeds that in the ambient water. In order to examine the response of PCB levels in water and fish to the two proposed remedial actions, a mathematical model was developed, calibrated and applied to assess the fate of PCBs in the Waukegan Harbor region. The model assessed the fate (movement and longevity) of PCB concentrations in the affected region by simulating the processes of water and solids transport and volatilization.

In developing the model framework, it was noted that Waukegan Harbor presents an essentially in-place pollutant situation. Since PCBs are adsorbed to solids, the predominant source of PCBs is the sediment layer underlying the water body and is primarily affected by the dynamic sediment processes of resuspension and deep burial. Ambient levels of PCBs in the water column are the net result of the competing processes of sediment loading in water due to resuspension of contaminated sediment and the settling of solids containing PCBs. These are the key processes simulated by the environmental model used in this assessment.

The environmental model is used to estimate the distribution of PCBs in the study area during and after the proposed cleanup activities. The accuracy or validity of the model projections is dependent on the ability of the model to adequately represent the system. This system representation was achieved and demonstrated through calibration of the model to measured data. The framework and parameters of the model utilized in these analyses are very similar to those of previous modelling efforts and the model calibration simulations compared well with observed data. From this base, the model applications were expanded to include potential ramifications of the two proposed remedial actions. From these projections possible PCB loads to the environment were estimated for each alternative.

The results of the investigations are divided into two categories. These are steady-state, "long-term responses; and "short-term" impacts. Of primary concern is the impact of actions associated with the process of dredging and excavation that are proposed in the ROD or IPC remedial alternatives.

Examination of the "long-term" results for both alternatives shows that the impacts of the harbor and the North Ditch are not expected to significantly extend beyond the immediate nearshore zone (shaded area in Figure 2). The effectiveness of the ROD alternative was very sensitive to the removal efficiency of the dredging operation, which was judged to be no greater than 90%. The results of the IPC alternative indicated that under the assumption that the proposed slurry wall will effectively isolate the PCB-containing sediments in Slip #3, the concentrations in the water column will approach background levels and the harbor will act as a sink for PCBs from Lake Michigan. It further showed that both the ROD and the IPC alternatives could result in decreases in PCB levels in fish from near the OMC site to levels in line with the FDA consumption guidelines. However, under the model assumptions, the ROD alternative would have to be nearly 100 per cent efficient in dredging operations in order that these guidelines be met.

"Short term" predictions of site conditions during remedial action implementation suggested that the dredging of Slip #3 under the ROD alternative could cause significant temporary increases in the PCB levels in the water column throughout the study area. Because of the high suspended solid levels that are expected, most of the PCBs will be in particulate form and subject to settling. A substantial portion of these exposed PCBs are expected to be confined to Slip #3 and the upper harbor due to the estimated effectiveness of the silt screens used during dredging. However, even under very optimistic conditions the volatilization of PCBs from the site will increase during remedial actions in Slip #3 under the ROD alternative and the rate of PCB export from the harbor could increase by an order of magnitude. This would result in temporary but significant elevations in the levels of PCBs in the surrounding atmosphere and nearshore lake.

Both the ROD and IPC plans include dredging of the upper harbor; however, the estimated impacts of dredging this area are much less significant. This is primarily due to much lower levels of PCBs associated with the sediments in this area. The projected water concentrations are also at high levels in the upper harbor but are expected to decrease in the lower harbor due to the effectiveness of the silt screen. The projections of the average PCB distribution obtained by the model simulations were utilized to estimate PCB levels in air, in the water column, and in resident fish in the lake for both of the remedial alternatives. Two processes which significantly impact the levels of PCBs in Waukegan Harbor and the transport of PCBs out of the harbor are the equilibrium partitioning of PCBs between solids and water and the volatilization of soluble PCBs from the water to the atmosphere.

3.3. Estimates of Human Exposure

According to the EPA (1984) Record of Decision, humans are potentially exposed to PCBs from the OMC site through ingestion of fish contaminated with PCBs from the site, volatilization of PCBs from the harbor and North Ditch area, drinking water from the emergency water intake of the Waukegan water supply that is located in the lower harbor area, and in a variety of recreational activities including boat washing and swimming. The potential extent of exposures and the resulting risks are evaluated for each of these exposure pathways.

<u>Exposure through inhalation</u>: PCBs originating from the OMC site may enter the air by evaporating from water in the harbor and North Ditch areas. Even though PCBs are relatively nonvolatile, the amounts of PCBs at the site make air a source of potentially significant exposure to the population in the area. Using meteorological data from the Zion Nuclear Power Plant located on Lake Michigan approximately 10 miles north of Waukegan and using volatilized amounts of PCBs from the harbor and North Ditch area as source terms, the movement of airborne PCBs from the site was estimated using the Industrial Source Complex atmospheric dispersion models. Air concentrations predicted by the models and human inhalation rates were used to estimate both maximum single-day exposures and cumulative exposures over seventy years of both persons living within 25 kilometers of the OMC site and persons working in the harbor area.

As expected, the highest estimates of PCB concentrations for the residential populations occur among persons living nearest to the OMC site. Because the number of people living in the area less than 1000 meters from the site is very small (15), this discussion will focus on potential exposure to the 10,726 persons living 1000 to 2000 meters from the site. As indicated in Table 1, the more probable estimates of lifetime exposure are 0.0087 nanogram/kilogram/day (ng/kg/day) for the IPC alternative and 0.45 ng/kg/day for the ROD with the worst case estimate being no more than twice the comparable more probable estimate in both cases. These estimates are based on the conservative assumption that persons will be exposed out-of-doors at their residences for 24 hours per day for 70 years. By way of comparison, average exposures in Chicago from inhalation of ambient air are estimated to be 3.4 ng/kg/day.

Of seven sites located in the vicinity of the harbor that were analyzed, workers in the area near the OMC offices located just north of Slip #3 (Figure 1) were estimated to have the highest potential exposures. Worst case estimates of average lifetime exposure to persons working in this area for 70 years are estimated as 0.15 ng/kg/day for the IPC alternative and 2.4 ng/kg/day for the ROD (Table 1), with most of this exposure occurring during cleanup operations. Therefore, even in the worst case, occupational exposures averaged over a lifetime are estimated to be less than those currently experienced by persons living in Chicago.

Estimates of the maximum daily inhalation exposures near the OMC site during cleanup operations are shown in Table 2. Larger maximum exposures are expected under the ROD than under the IPC alternative. During the cleanup, under the ROD alternative, the expected maximum daily exposure is approximately 3 times that expected under the IPC. This higher level is the result of evaporation from Slip #3 and the dewatering lagoons as proposed under the ROD alternative.

<u>Exposure through ingestion of fish</u>: The potential of exposure to PCBs from the OMC site through ingestion of fish is particularly important because fish are known to bioaccumulate PCBs and the waters of Lake Michigan near Waukegan are heavily fished. Since there are very few fish in Waukegan Harbor, it was assumed that although people might occasionally eat a fish from the harbor, they would not do so regularly. Accordingly, worst case maximum single-day exposures are based upon eating fish from the harbor, while more probable single-day exposures and average lifetime exposures are based on PCB levels in fish from the portion of the lake estimated to be impacted by PCBs from the harbor (shaded area in Figure 2). PCB levels in lake fish were estimated by applying a bioaccumulation factor to estimated levels of PCBs in the portion of Lake Michigan impacted by the OMC site and taking into account the percent of time fish spend in similar areas of the lake. For fish caught in Waukegan Harbor, actual data on PCB levels in fish from the harbor were utilized. Worst case estimates of average lifetime exposure are based on an annual fish consumption of 47 pounds and more probable estimates upon an annual consumption of 7.4 pounds per year. All of these fish are assumed to be caught in the two square mile area of Lake Michigan estimated as being impacted by PCBs from the harbor (Figure 2).

The higher estimates of exposure through ingestion of fish are from the ROD (Tables 1 and 2). Considering more probable estimates, the IPC is estimated as being approximately 6 times more effective in reducing exposure from ingestion of fish than the ROD. The greater predicted effectiveness of the IPC is due principally to the projected higher efficiency of the IPC in curtailing releases from the most heavily contaminated areas in Slip #3. Under the ROD, PCB levels in Slip #3 are projected to be reduced ten-fold, whereas under the IPC, Slip #3 will be completely closed off.

Exposure through dermal contact: Concern is expressed in the EPA (1984) Record of Decision that persons might be exposed dermally to PCB-containing sediments from the harbor. To evaluate the possible extent of such exposure a scenario was studied in which persons are assumed to be exposed through washing PCB-containing mud and silt from boats.

Estimation of exposure through washing boats requires judgments regarding several parameters, including: the amount of mud, silt, or sand a person could get on his body, the amount of clothing a person would be wearing and how this would affect exposure, and the amount of PCBs in the mud, silt, or sand that could be absorbed through the skin and into the body. In the absence of definitive information on such parameters, they were estimated conservatively, i.e., so that exposures are probably overestimated. For example, worst case estimates of maximal single-day exposure are based on the assumptions that 80% of a person's body is covered with the same concentration of soil as would be found on the hands of a small child playing outdoors, and that 100% of the PCBs is absorbed through the skin. Worst case estimates of maximal daily exposure are based on the assumption that silt and mud from a boat contain the same level of PCBs (1737 ppm) as sediments from the area of Slip #3 near Larsen Marine. More probable estimates are derived by assuming mud and silt levels equal to the sediment levels from the lower harbor. Worst case estimates of average lifetime exposure are derived by assuming twenty boat washings in a lifetime, one of which involves silt and mud PCB levels equal to those near Larsen Marine and the remainder involves levels commensurate with PCB levels in the lower harbor. Under the worst case assumptions, dermal exposure under the ROD is higher than the IPC by a factor of approximately 2 (Table 1).

Exposure through drinking water: The City of Waukegan maintains an emergency drinking water intake in Waukegan Harbor. Although this intake is seldom used, it nevertheless is an integral part of the water supply. Should the city need to utilize the emergency intake, PCBs from the harbor could be introduced into the drinking water system. Historical data on the frequency of use of the emergency water intake and estimates of PCB water concentration levels were utilized to calculate exposure to persons drinking water from this intake, assuming that no PCBs would be removed during the water treatment process. This analysis indicated that the exposure through this route is likely to be very minimal (Tables 1 and 2).

Exposure through swimming: Exposure to PCBs during swimming could occur through dermal uptake and through ingestion of PCB-containing water. Estimates of total lifetime exposures are based on the assumption that a person swims regularly near the public beach for 30 years. Worst case single-day exposures are estimated by assuming that workers might occasionally fall into the harbor. Exposures through this route are estimated as being very minimal (Tables 1 and 2).

4. Hazard Assessment

A thorough review of the PCB literature was conducted to identify the potential health effects that PCBs might cause and to determine the dose response relationships between exposure and effect. Since appropriate quantitative human data on PCB toxicity are not available, assessment of the potential hazards from PCB exposure was based primarily upon animal bioassay data. Available mammalian toxicity data for PCB mixtures and for specific PCB compounds were qualitatively described and critically reviewed. Types of health effects considered include carcinogenic effects (cancer) and noncarcinogenic effects such as teratogenic effects (birth defects or malformations), fetotoxic effects (alterations in growth and development of the fetus), other reproductive effects (infertility or miscarriage), immunological effects, and a variety of effects collectively referred to as systemic effects and including damage to the liver, the gastrointestinal tract, and the central nervous system.

The development of toxicity in experimental animals appears to be related to the type and amount of PCB administered, the animal species tested, and the route and length of exposure. In the majority of toxicity studies evaluated, PCBs were administered to the test animals in their diet. No studies were available for review in which animals were exposed by inhalation. The major systemic effects observed in experimental animals include damage to the liver, to the skin and related dermal tissues, and to the gastrointestinal tract.

The major adverse effects on reproductive capability in experimental animals included decreased litter sizes, decreased litter survival, increased abortions and resorptions, and at high doses, maternal death, although not all of these effects have been shown to be produced by all PCB mixtures. All mixtures of PCBs included in the reviewed literature, except Aroclor 1221, resulted in deleterious effects to the immune system of test animals.

In previous tests for carcinogenicity, PCB compounds containing 60% chlorine have been fed to rats at 100 ppm in longterm tests. The results indicated a definite relationship between the PCB-containing diets and the increased incidence of both benign and malignant liver tumors. Aroclor 1254 (containing 54% chlorine) has also been tested in rats by the National Cancer Institute, but conclusions from this study are uncertain. Although the conclusion in the original study indicated that Aroclor 1254 was not carcinogenic in rats under the specified test conditions (up to 1000 ppm for 24 months), later reevaluations of the data conclude that Aroclor 1254 was indeed carcinogenic in the NCI bioassay.

For each type of adverse effect (systemic, reproductive, teratogenic, fetotoxic, or carcinogenic) the study that demonstrated, toxicologically and statistically, the greatest toxic potential from exposure to the specified PCB was selected for making quantitative estimates of risk. In keeping with the "worst case" approach, results of experimental studies were interpreted conservatively; for example, whenever there were two plausible but conflicting interpretations of experimental results, the interpretation providing the highest risk to humans was generally used.

5. Risk Characterization

Risk characterization is the quantitative estimation of any increased risks to human health from the exposures estimated in the exposure assessment. The first phase of risk characterization is dose response assessment, which involves determining quantitatively the relationship between levels of exposure and the likelihood of resulting health effects.

<u>Noncarcinogenic effects:</u> Estimates of risk for noncarcinogenic health hazards are evaluated by comparing the estimated levels of human exposure with "no observable effect levels" (NOELs) derived from animal toxicity studies to arrive at margins of safety (MOS) for systemic, reproductive, fetotoxic, immunologic, or teratogenic effects. The MOS are generally calculated by dividing the NOEL derived in a chronic bioassay in the most sensitive species by the maximum daily human exposure. In the absence of an experimentally derived NOEL, the lowest dose at which an effect occurred, the "lowest effect level" (LEL), was used. In this analysis, margins of safety for noncarcinogenic effects were derived from chronic bioassays in which primates were fed Aroclor 1248 in the diet (Allen *et al.*, 1979). For reproductive, teratogenic, and immunological effects a NOEL was determined, but for systemic and fetotoxic effects, an LEL was used. The margin of safety is not a measure of dose, but rather is a factor that denotes the relationship between the maximum daily human exposure estimate and the NOEL. Applying the guidelines proposed by the National Academy of Sciences for evaluation of Allowable Daily Intakes, a margin of safety of 100 or greater applied to a NOEL and 1000 or greater applied to an LEL may indicate that the human exposure is small (as compared to the NOEL) and that the risk to humans may be negligible. The larger the margin of safety (the smaller the estimated human exposure compared to the animal NOEL), the lower the potential risk to human health. The actual value of the margin of safety that would be considered safe will vary with the quality of the experimental data from which the NOEL was derived.

The margins of safety calculated in these analyses are conservative comparisons because they compare generally brief (often single-day) human exposure to repeated daily exposures in animals that generally last for a significant portion of the normal animal lifespan.

Carcinogenic effects: Estimates of cancer risk are obtained by fitting mathematical dose response models to cancer bioassay data. The fitted models are used to predict risks at estimated human dose levels, which are typically much smaller than the experimental doses in the animal bioassays. The multistage dose response model (Crump *et al.*, 1977; Crump, 1984) was used in the present study. This model has been widely used by federal agencies [e.g., the Environmental Protection Agency (USEPA, 1980), the Occupational Safety and Health Administration (OSHA, 1983), and the Center for Disease Control (Kimbrough *et al.*, 1984)] and other state and private groups to assess risk from low exposures to carcinogens. The multistage model embodies the assumption that no level of exposure is completely safe and consequently even a single PCB molecule theoretically could cause cancer.

Potency estimates were derived by applying the multistage model to a total of twenty cancer data sets from all of the appropriate studies identified. The potency estimate of 0.639 $(mg/kg/day)^{-1}$ was selected for estimating risk. This value was derived from combined data on total liver tumors reported in the Kimbrough *et al.* (1975) and Norback and Weltman (1985) studies and was the highest of the statistical 95% upper limits on potency of the twenty such potency values calculated. Risk estimates were converted from animals to humans by assuming that a given dose rate expressed in mg/kg/day gives the same risk in animals and humans. For the relatively low PCB exposures which are estimated in this analysis, the extra risk of cancer from PCBs can be estimated by simply multiplying the potency estimate of 0.639 $(mg/kg/day)^{-1}$ by the estimated average lifetime dose of PCBs in mg/kg/day. Cancer risk estimates made in this manner are considered to represent "reasonable upper bounds on risk" rather than precise estimates. Such limits are applied widely by federal agencies to set upper limits to carcinogenic risks (USEPA, 1980; OSHA, 1983; Kimbrough *et al.*, 1984).

EPA (1983) estimated a potency value of 4.34 $(mg/kg/day)^{-1}$ which is about seven times higher than the value of 0.639 $(mg/kg/day)^{-1}$ used in this assessment. This difference occurs because EPA converted risk from animals to humans by assuming that a given dose rate expressed in mg/m^2 body surface area/day gives the same risk in animals and humans. The data available that address this subject indicate to us that the mg/kg/day approach applied in this analysis is generally more accurate than that used by EPA. Also, crude estimates of carcinogenic risk made from epidemiological data on human populations exposed to PCBs are more nearly consistent with a potency of 0.639 $(mg/kg/day)^{-1}$ than with EPA's estimate. Estimates of risk provided in this analysis from specified exposures can be converted to those that would result from applying the EPA approach by multiplying the cancer risk estimates contained herein by $4.34/0.639 = 6.8$.

<u>Results</u>: Table 1 provides estimates of cancer risk associated with the average daily lifetime exposures estimated earlier. Table 2 lists margins of safety (MOS) for reproductive effects from maximum daily exposures. Reproductive effects had some of the lowest MOS of the non-carcinogenic effects studied and were selected for inclusion in this summary as representative of other noncarcinogenic effects. MOS for all

noncarcinogenic effects are recorded in the main document.

Lifetime worst case carcinogenic risks from drinking water from the harbor intake and swimming are all less than six per 10 billion for both remedial alternatives. Similarly, MOS associated with these activities are all greater than 30000.

Lifetime carcinogenic risks from inhalation are on the order of one per million for the ROD alternative and from ten to one hundred times smaller for the IPC alternative. MOS for single-day, more probable, occupational inhalation exposure are on the order of 100 for the IPC alternative and 30 for the ROD alternative.

More probable lifetime carcinogenic risks for dermal exposure (washing boats) are less than one per million (Table 1). It should be kept in mind in evaluating these estimates that a number of seemingly conservative assumptions concerning exposure and dermal uptake are used in estimating dermal exposures. Also, in calculating MOS, single-day human exposures are being compared to effects seen after repeated exposures in animals.

The results in Tables 1 and 2 indicate clearly tnat the largest potential risk to humans comes from eating fish containing PCBs from the harbor. More probable estimates of risk under the ROD alternative are two per million and under the IPC alternative are less than one per million. Similarly, MOS values calculated for the ROD and IPC alternatives are greater that one.

6. Discussion

A number of the assumptions used in estimating exposure are likely to result in overestimation of the exposure to most individuals. For example, the worst case exposures from eating fish are derived from the assumptions that an individual will eat 47 pounds of fish each year for 60 years, all of which are caught from the two-square mile area of Lake Michigan that is estimated to be affected by PCBs from the harbor. Similarly, worst case estimates of dermal exposure are based on estimates of dermal exposure and uptake which are likely to be highly conservative for most situations.

The results of this assessment are perhaps most useful for gauging the relative degrees of risk posed by the ROD and IPC remedial alternatives. Many of the uncertainties associated with estimates of risks are less important when comparing risks from the two alternatives, because many steps in the estimation process are common to both alternatives, and uniform approaches were followed for these steps. This includes all of the steps involving the use of toxicological data in dose response assessment, as well as those discussed in the previous paragraph. Steps which affect comparisons among alternative remedial actions involve only the assessment of environmental concentrations of PCBs.

One of the most critical assumptions affecting comparisons among remedial actions is that dredging will remove 90% of PCBs from the harbor sediments. Based on the information available at this time, this appears to be an optimistic estimate and actual removal may not achieve this high level of efficiency; therefore significant amounts of contaminated sediments will probably remain in Slip #3 and PCBs will continue to be exposed and transported to the environment after completion of the

ROD action. In contrast, the IPC alternative involves the isolation of the highly contaminated sediments in Slip #3 through construction of a slurry wall between Slip #3 and the upper harbor area. As a result, the IPC alternative is estimated to be much more effective in preventing the transport of PCBs to the environment and ultimately in reducing sediment, water, and fish concentrations of PCBs.

There is quantitative data to indicate that PCBs degrade or undergo deep burial at a constant rate. Water data collected monthly over the past ten years indicate that average PCB levels in water in Slip #3 have been decreasing by 50% or more every five years. This suggests that a natural recovery process may be occurring whereby the median PCB concentrations decrease by 50% every five years, *i.e.*, PCBs in this environmental compartment appear to have a half-life of five years. The five year half-life for the effective PCB concentrations in harbor sediments is plausible, but was not applied to either the ROD or IPC alternatives. Had the five year half-life assumption been applied to the ROD and IPC, cancer risks resulting from sediment concentrations would have been reduced. For example, applying the five year half-life assumption to the IPC alternative would have resulted in more probable estimates of lifetime cancer risk from eating fish being reduced from 0.28 per million to 0.004 per million. On the other hand, maximum daily exposures and corresponding MOS would be unaffected by assuming a finite half-life because the maximal single-day exposure could occur before PCB degradation occurs in sediment.

A complete assessment of the comparative risks from the various alternatives should consider special risks associated with cleanup alternatives, such as risks of accidents. The ROD alternative calls for removal in sealed drums to an EPA-approved landfill of all sediments containing PCB levels in excess of 10,000 ppm. It is estimated that 570 truckloads may be required to move this amount of sediment. In an EPA feasibility study, two landfills were proposed for the permanent disposal of the PCB contaminated sediments. Of these two, only the landfill located in Williamsburg, Ohio is licensed to accept PCBs. Based on distances from Waukegan to this landfill, types of roads that would be traversed, and state-specific accident rates for trucks, it is estimated that the probability of an accident involving at least one fatality while transporting this material is 380 per million. Although not evaluated in this study, any accident, fatal or otherwise, could result in release of PCBs to the environment and exposure to humans. There is likely to be considerable dermal and inhalation exposure to workers also involved in dredging and other cleanup operations.

The risk estimates appearing in Tables 1 and 2, particularly those pertaining to cancer, may be difficult to place in perspective. To aid in this process, listed in Table 3 are some risks of cancer and accidental death from activities with which most individuals may be more familiar. The cancer risks were calculated by applying the same methods (dose response model, etc.) to health effect data as were applied in the risk assessment reported in this summary.

Table 1

Estimated Lifetime Exposures and Corresponding Cancer Risks

Exposure Route/ Alternative Action	More Probable Estimates: Average Lifetime Exposure (ng/kg/day)	More Probable Estimates: Risk per 1 Million Persons Exposed	Worst Case Estimates: Average Lifetime Exposure (ng/kg/day)	Worst Case Estimates: Risk per 1 Million Persons Exposed
Dermal				
ROD	0.53	0.34	1.3	0.84
IPC	0.53	0.34	0.76	0.49
Drinking Water				
ROD	0.00048	0.00031	0.00095	0.00061
IPC	0.000007	0.0000045	0.00013	0.000083
Swimming				
ROD	0.000026	0.000017	0.000087	0.000056
IPC	0.0000043	0.0000027	0.000041	0.000026
Ingestion of Fish				
ROD	2.9	1.9	94.0	60.0
IPC	0.44	0.28	51.0	33.0
Inhalation Residential (1000-2000 meters)				
ROD	0.45	0.29	0.70	0.45
IPC	0.0087	0.0056	0.017	0.011
OMC - Offices				
ROD	1.5	0.93	2.4	1.5
IPC	0.083	0.053	0.15	0.093

Table 2

Estimated Maximum Daily Exposures and Corresponding Margins of Safety for Reproductive Effects

Exposure Route/ Alternative Action	More Probable Estimates: Maximum Daily Exposure (ng/kg/day)	More Probable Estimates: MOS	Worst Case Estimates: Maximum Daily Exposure (ng/kg/day)	Worst Case Estimates: MOS
Dermal				
ROD	670	4.9	21000	1.6
IPC	670	4.9	6600	5.0
Drinking Water				
ROD	0.48	68000	0.96	35000
IPC	0.0073	4500000	0.13	250000
Swimming				
ROD	0.48	68000	0.96	35000
IPC	0.0073	4500000	0.13	250000
Ingestion of Fish				
ROD	160	210	12000	2.7
IPC	24	1400	1600	21
Inhalation OMC - Offices				
ROD	1000	33	1600	21
IPC	350	94	600	55

Table 3

Lifetime Risks Per Million Persons[a]

Smoking cigarettes regularly [lung cancer only]	88,000
Accident from working for 40 years	
in mining and quarrying	24,000
in construction	15,600
in manufacturing	2,400
in agriculture	18,400
(farm residents only)	6,280
Airline pilot (cancer from cosmic radiation)	899
Drinking one diet soft drink per day [saccharin](cancer)	170
One hour per day exposure to passive cigarette smoke at work (lung cancer)	200
Living in a brick house [radiation, except radon](cancer)	56
Chest x-rays during life [radiation, U.S. average](lung cancer)	41
Eating peanut products [aflatoxin, U.S. average] (liver cancer)	11
Keeping a clock with a radium dial in the bedroom for 5 years (cancer)	9
Having a chest x-ray (lung cancer)	1.5
Spending a day in the Rocky Mountains (cancer from cosmic radiation)	0.13
Taking a single airplane flight (cancer from cosmic radiation)	0.06

[a]Estimates of lifetime risks calculated in-house at K S Crump/Clement.

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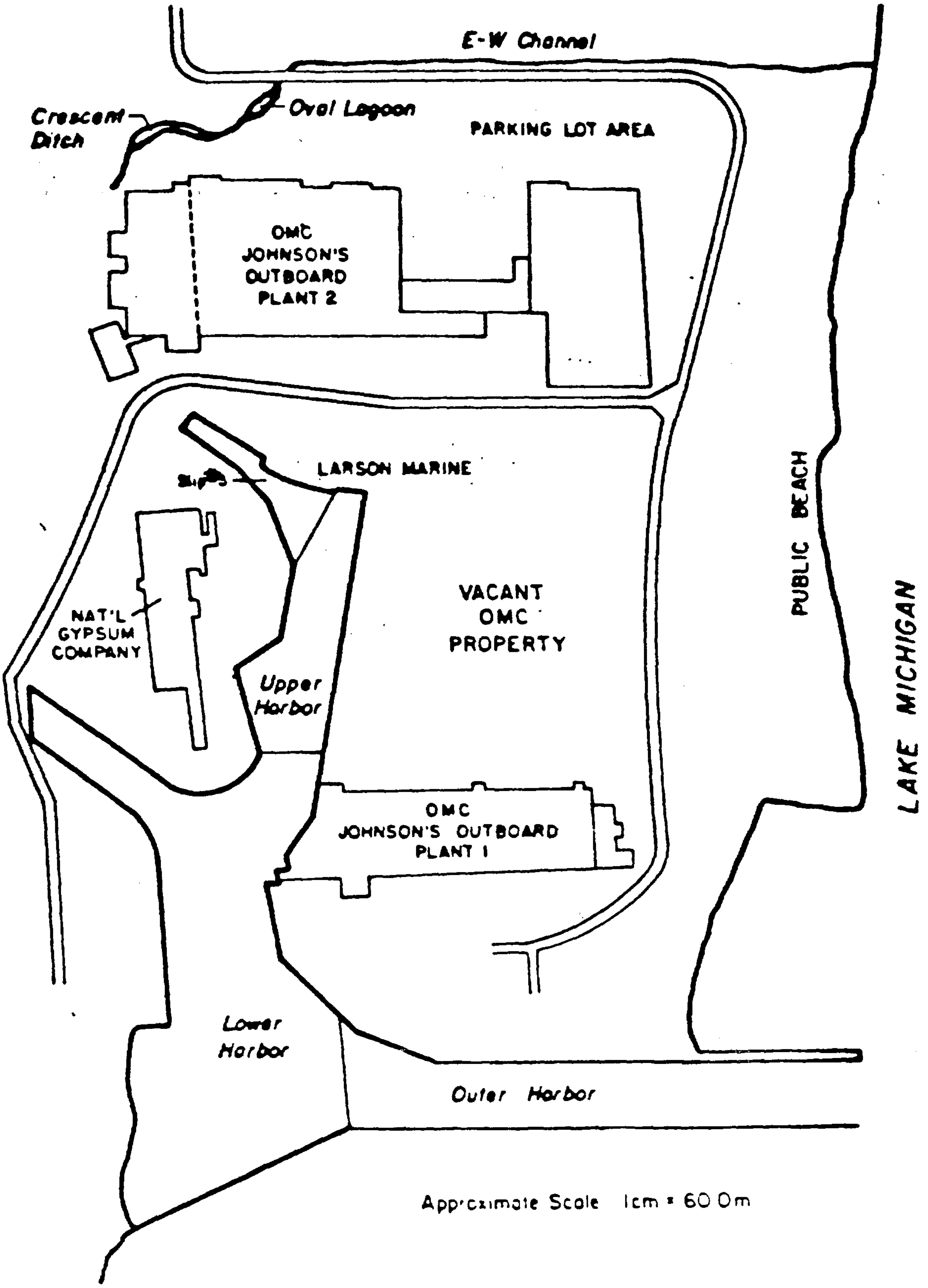

Figure 1. Map of Waukegan Harbor Area

Figure 2. Segmentation for Reported Average Model Results